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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,990

Applicant(s)

BESSE JEROME ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of Applicant's amendment, filed on June 18, 2002, is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 29, the phrase "Composition is solid form and forming a composition according to claim 21 by mixing with water" renders the claim indefinite, because the composition is not defined and it is not clear what ingredients are mixed with water.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over N'Guyen et al. in view of Lanzerdörfer et al.

The claimed invention refers to a composition comprising flavonoids and a vehicle and a method comprising administering said composition.

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N'Guyen et al. provides a method for treating damage caused to the skin and mucous membranes by radiation or free radicals, said method comprising applying to the skin or mucous membranes a composition comprising a product having peroxidase activity and an antioxidant (See e.g., col. 1, line 55 to col. 2, line 19). N'Guyen et al. teaches that polyphenols are agents capable of neutralizing oxygen radicals and includes flavonoids, and in particular tangeretine, rutin and quercetin, among the polyphenols used in the invention (See e.g., col. 3, line 61 to col. 4, line 67). N'Guyen et al. teaches that the compositions of the invention may be in the form of solutions or gels and include adjuvants, such as thickeners, in the compositions (See e.g., col. 7, lines 8-27). The anti-wrinkle dermapharmaceutical gel disclosed in Example 7 comprises synperonic PE/L62, which is Poloxamer 182.

Thus, N'Guyen et al. discloses compositions comprising flavonoids, thickeners and poloxamer and methods comprising applying said compositions to the mucous membranes. N'Guyen et al. does not specify the kind of radiations, which cause damage to the skin.

Lanzerdörfer et al. discloses topical formulations for the prophylaxis and treatment of skin diseases, including herpes labialis, which is a disease of the mucous membrane, and teaches that the compositions of the invention comprise flavonoids (See e.g., col. 1, line 1 to col. 2, line 67). Lanzerdörfer et al. includes radiodermatitis caused by ionizing radiation therapy among the skin diseases treated by the compositions of the invention (See e.g., col. 3, lines 39-49).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the compositions disclosed by N'Guyen et al. to mucous

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membranes for the treatment of dermatosis caused by radiation or other invasive treatment, as taught by Lanzerdörfer et al. The expected result would have been a successful composition and method for the treatment of mucous membrane diseases. Because of the teachings of N'Guyen et al. and Lanzerdörfer et al., that flavonoids may be combined with thickeners in topical compositions and are effective in the treatment of skin and mucous membrane diseases, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods disclosed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed on June 18, 2002 have been fully considered but they are not persuasive.

Applicant argues that the prior art does not teach or suggest a composition, which is liquid at room temperature and gels at mucous membrane temperature. In response to said argument, it is noted that N'Guyen et al. discloses compositions comprising flavonoids, thickeners and poloxamer and methods comprising applying said compositions to the mucous membranes, as claimed by Applicant. The "mere recitation of newly-discovered function or property, inherently possessed by things in the prior art does not cause claim drawn to those things to distinguish over the prior art; Patent Office can require Applicant to prove that subject matter shown to be in the prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be

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inherent characteristic of prior art; this burden of proof is applicable to product and process claims reasonably considered as possessing allegedly inherent characteristics". (See *In re Best, Bolton, and Shaw* (CCPA) 195 USPQ 430. 10/13/1977). It is not necessary for the prior art to teach each and every property of the claimed compositions and methods. The prior art disclosure of the same compositions and method of application claimed by Applicant inherently provides the same results. The burden is shifted to Applicant to show that the compositions provided by the prior art would not inherently have the property of being liquid at room temperature and gelling at mucous membrane temperature, as claimed by Applicant.

7. In response to Applicant's argument, that the prior art does not teach radiomucositis and chemomucositis, it is noted that N'Guyen provides a method of preventing damage to the mucous membranes comprising applying a composition comprising flavonoids, thickeners and poloxamer, as claimed by Applicant, and Lanzerdörfer et al. discloses topical formulations comprising flavonoids for the prophylaxis and treatment of skin diseases, including herpes labialis, which is a disease of the mucous membrane, and photodermatitis. Thus, the prior art teaches that compositions comprising flavonoids, thickeners and poloxamer are effective in the treatment of mucous membrane diseases, including those caused by radiation and chemotherapy.

Conclusion

8. Claims 20-29 are rejected.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

August 16, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY/CENTER 1600